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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,813

01/29/2007

Wilda Laux

E3697-00044

1928

53897 7590 05/21/2010
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EXAMINER

MCGARRY, SEAN

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

05/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,813	Applicant(s) LAUX ET AL.	
	Examiner Sean R. McGarry	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 102-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 102-121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Official Action is in response to the papers filed 6/22/09, 1/05/10, and 2/09/10. Applicant has canceled all pending claims and has added new claims 102-121.

Election/Restrictions

Applicant's election with traverse of "chemical trauma" and antisense in the reply filed on 1/05/10 is acknowledged. The traversal is on the ground(s) that there is no search or examination burden. The requirement of II of the species requirement is moot in view of the amendment to claim 17. The examiner will examine both "chemical" and mechanical" trauma. Sequences other than SEQ ID NO:1 and 12 remain withdrawn.

Claims 102-121 are pending and are under examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1635

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 73-78, 80, 81 and 98-101 **were** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-119 of copending Application No. 11/510,280. This provisional rejection is moot in view of the cancellation of the subject claims.

Claims 73-78, 80, 81, and 98-101 **were** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-189 of copending Application No. 11/510,498. This provisional rejection is moot in view of the cancellation of the subject claims.

Claims 69-73, 77-80, and 86-90 **were** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-44 of copending Application No. 11/512,725. This provisional rejection is moot in view of the cancellation of the subject claims and the abandonment of 10/512,725.

Claims 69-73, 77-80, and 86-90 **were** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-70 of copending Application No. 11/512,730. This provisional rejection is moot in view of the cancellation of the subject claims.

Claims 69-73, 77-80, and 86-90 **were** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-72 of copending Application No. 11/512,735. This provisional rejection is moot in view of the cancellation of the subject claims.

Claims 73-78, 80, 81, and 98-101 **were** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-70 of U.S. Patent No. 7,098,190. This rejection is moot in view of the cancellation of the subject claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 73-78, 80, 81 and 98-101 **were** rejected under 35 U.S.C. 102(e) as being anticipated by Becker et al [US 20070060538].

This rejection is moot in view of the cancellation of the subject claims.

Claims 73-78, 80, 81 and 98-101 **were** rejected under 35 U.S.C. 102(e) as being anticipated by Becker et al [US 20080221051].

This rejection is moot in view of the cancellation of the subject claims.

Claims 69-81 and 98-100 **were** rejected under 35 U.S.C. 102(e) as being anticipated by Becker et al [US 20080249041].

This rejection is moot in view of the cancellation of the subject claims.

Art Unit: 1635

Claims 69-81 and 98-100 **were** rejected under 35 U.S.C. 102(e) as being anticipated by Becker et al [US 20070072819].

This rejection is moot in view of the cancellation of the subject claims.

Claims 69-81 and 98-100 **were** rejected under 35 U.S.C. 102(e) as being anticipated by Becker et al [US 20070072820].

This rejection is moot in view of the cancellation of the subject claims.

Claims 73-78, 80, 81 and 98-101 **were** rejected under 35 U.S.C. 102(e) as being anticipated by Becker et al [US 7,098,190].

This rejection is moot in view of the cancellation of the subject claims.

Claims 77,78, 80, 81, and 98 **were** rejected under 35 U.S.C. 102(b) as being anticipated by Qiu et al [Current Biology Vol.13:1697-1703, 2003].

This rejection is moot in view of the cancellation of the subject claims

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 81-83 and 86-101 were rejected under 35 U.S.C. 103(a) as being obvious over Becker et al [US7098190], and Becker et al [US 20080221051], and Becker et al [US 20080249041], and Becker et al [US 20070072819], and Becker et al [US 20070072820], and Becker et al [US 20070060538], and Qiu et al [Current Biology Vol.13:1697-1703, 2003].

This rejection is moot in view of the cancellation of the subject claims.

A new ground of rejection under 35 U.S.C. 103(a) is applied below:

Claims 102-121 are rejected under 35 U.S.C. 103(a) as being obvious over Becker et al [US 20080249041], and Becker et al [US 20070072819], and Becker et al [US 20070072820], in view of Taub et al [Exp. Eye Res. Vol.73:291-302, 2001], and Qiu et al [Current Biology Vol.13:1697-1703, 2003].

The applied patent publication references all have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed

Art Unit: 1635

but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The invention is as clearly set forth in the claims.

Becker et al[US20080249041] have disclosed the use of antisense compound targeted to various connexins including human connexin 43 and 31.1 for the treatment of various conditions associated with wounds including eye wounds[connexin 31.1]. It has been disclosed the inhibition of connexins, including connexin 43 for the treatment of wounds including trauma, surgical incisions, reduction of scar formation and reduction of inflammation. It has disclosed that the tissue can be skin or nervous tissue including spinal chord and optic nerve and the eye. Becker et al have specifically disclosed the use of SEQ ID NO: 1 which is the same as the instant SEQ ID NO: 1 which targets a human connexin 43 and would target the instant SEQ ID NO: 12. Becker et al disclose treating for at least 24 hours and further for longer periods. See

Art Unit: 1635

claims 37-44 as well as the entire specification which describes the claimed invention throughout.

Becker et al[US 20070072819] have disclosed the use of antisense compound targeted to various connexins including human connexin 43 and 32 for the treatment of various conditions associated with wounds including eye wounds[connexin 32]. It has been disclosed the inhibition of connexins, including connexin 43 for the treatment of wounds including trauma, surgical incisions, reduction of scar formation and reduction of inflammation. It has disclosed that the tissue can be skin or nervous tissue including spinal chord and optic nerve and the eye. Becker et al have specifically disclosed the use of SEQ ID NO: 1 which is the same as the instant SEQ ID NO: 1 which targets a human connexin 43 and would target the instant SEQ ID NO: 12. Becker et al disclose treating for at least 24 hours and further for longer periods. See claims 37-44 as well as the entire specification which describes the claimed invention throughout.

Becker et al[US 20070072820] have disclosed the use of antisense compound targeted to various connexins including human connexin 43 and 26 for the treatment of various conditions associated with wounds including eye wounds[connexin 26]. It has been disclosed the inhibition of connexins, including connexin 43 for the treatment of wounds including trauma, surgical incisions, reduction of scar formation and reduction of inflammation. It has disclosed that the tissue can be skin or nervous tissue including spinal chord and optic nerve and the eye. Becker et al have specifically disclosed the use of SEQ ID NO: 1 which is the same as the instant SEQ ID NO: 1 which targets a human connexin 43 and would target the instant SEQ ID NO: 12. Becker et al disclose

Art Unit: 1635

treating for at least 24 hours and further for longer periods. See claims 37-44 as well as the entire specification which describes the claimed invention throughout.

The Becker et al references above have all taught the use of connexin antisense including antisense to connexin 43 in the treatment of a wide range of wound types in a wide range of tissues. It has been taught to target connexin 32, 26 and 31.1 specifically for the treatment of eye wounds.

None of the Becker references specifically teach connexin 43 as a target for treating ocular wounds.

Traub et al have taught a correlation in the expression of connexin 43 following excimer laser photorefractive Keratectomy. This was a study in wound repair of the eye. Traub et al have taught the connexin 26 and 43 are expressed in the cornea in response to eye wounding. At page 300, for example it is taught "Furthermore, wounding caused up-regulation and rearrangement of both Cxs around the original wound edges including the limbal areas. [t]his was manifested by the loss of the original segregation and spreading to upper layers of the particulate reactions after 24 hr and uneven concentration of Cxs in the basal layer after 3 days. Similar up-regulation and overlapping relocation of Cx 26 and Cx43 expression has been demonstrated in rodent skin during rapid epidermal growth and differentiation forced by mitogen activation . . ." This appears to indicate that the function of Cx43 in skin eye tissue is similar.

Qui et al assert that in view of their findings of wound treatment with connexin 43 antisense "This approach is likely to have widespread therapeutic applications in other injured tissues. . ." See conclusion paragraph at page 1700-1702, for example.

Art Unit: 1635

The art has therefore taught that down regulation of connexin proteins in wound promotes wound healing. The prior art has shown that various types of wounds(including surgical) in various tissues can be effectively treated with antisense to connexins including connexin 43. The prior does not specifically teach the use of connexin 43 in the treatment of eye wounds, but has taught the use of antisense to connexin 26, 31.1 and 32 in treating eye wounds. The prior art has, however shown that connexin 43 is correlated with eye wounding and furthermore has shown that the action of connexin 43 in eye wound is similar to the action of connexin 43 in other tissues. Since the art has clearly taught the connexin 43 can be targeted by antisense to facilitate wound healing and since the art has taught that connexin 43 expression is also implicated in eye wound response and furthermore since the art has taught the targeting of other connexin proteins in eye wound healing one in the art would have been motivated to and have had a reasonable expectation of success to treat eye wounds with antisense compounds targeting connexin 43.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry
Primary Examiner
Art Unit 1635

/Sean R McGarry/
Primary Examiner, Art Unit 1635